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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,921	07/10/2002	Hiroshi Kido	2002-0319A	2978

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EXAMINER	
HILL, MYRON G	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 02/20/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,921	KIDO ET AL.	
	Examiner	Art Unit	
	Myron G. Hill	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1- 5 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1- 5 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/10/02.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1- 5 are under consideration.

Information Disclosure Statement

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1- 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to a method but there are no distinct method steps that set fourth and define the steps of the method and there is no conclusion that indicates that the method results in the method finding a substance with anti-influenza virus activity.

Claims 2- 5 set fourth at least one method step. However, it is not clear in these claims that the reaction conditions permit the reaction to occur. It is not clear in these claims what the result indicates (In claim 2, does an increase of the amount of F1 and F2 indicate that the compound does have anti-influenza activity?). It is not clear in these claims what the comparative basis is for determining (for example, what is the index

based on in claim 4?). Claims 2- 5 lack a conclusion stating that they result in the finding of a compound that has the anti-influenza activity.

It is not clear what is meant by the term "probe" in claims 1- 5. In claims 4 and 5, it is not clear what "a cell infection unit" is.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1- 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kido *et al.*

The claims are drawn to methods of determining if a compound has anti-protease activity in which the protease interferes with influenza or Sendai virus infectivity and the protease used to test for antiviral agents is miniplasmin. Miniplasmin is used a probe to test for antiviral agents in the methods.

Kido *et al.* disclose that miniplasmin is a protease that is involved with infectivity of influenza and Sendai viruses and is almost as effective as trypsin in activating (making infectious) these viruses (page 240, top of column 1). Kido *et al.* were lead to miniplasmin because anti-Clara trypase antibody was not effective in completely blocking infectivity of the virus (page 237, lower part column 2). Kido *et al.* suggest that

therapies using miniplasmin inhibitors may also be useful in treating or preventing infections with influenza and Sendai viruses (page 242, lower part column 2).

Purification, inbitibitors, and protease properties of miniplasmin are known in the art as cited by Kido *et al.*

One of ordinary skill in the art at the time of invention would have known the importance of trypsin for the infectivity of influenza and Sendai viruses and would have been motivated to find inhibitors of miniplasmin to act against influenza and Sendai viruses knowing that it also leads to making infectious virus. One of ordinary skill in the art at the time of invention would have been able to test the viruses for infectivity or for protease cleavage of influenza and Sendai virus HA or F proteins, respectively, using miniplasmin as a probe. One of ordinary skill in the art at the time of invention would have known that a substance that interferes with miniplasmin tested on Sendai virus will have the same effect on influenza virus because both influenza and Sendai virus use miniplasmin to cleave HA or F proteins, respectively, to become infectious virus.

Thus, it would be *prima facie* obvious to assay for a substance that anti-influenza properties using miniplasmin as suggested by Kido *et al.* with the expectation of success because Kido *et al.* teach that miniplasmin is important in making infectious influenza virus.

Thus, the invention is not patentable over Kido *et al.*

Conclusion

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Myron G. Hill whose telephone number is 571-272-0901. The examiner can normally be reached on 9am-6pm Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Myron G. Hill
Patent Examiner
February 17, 2004

JEFFREY STUCKER
PRIMARY EXAMINER